UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	)	
Plaintiff,	)	
v.	)	Civ. No. 20-11217
REGENERON PHARMACEUTICALS, INC.,	)	
Defendant.	)	

COMPLAINT

1. Since 2013, the Medicare Part B program has spent over $11.5 billion on Eylea, an injectable macular degeneration drug that typically costs over $10,000 per year. In 2013 and 2014 alone, Medicare paid $1.9 billion for the drug. Eylea's manufacturer, Regeneron Pharmaceuticals, Inc. ("Regeneron"), achieved these sales in part by funneling tens of millions of dollars through a co-pay foundation, the Chronic Disease Fund ("CDF"), to ensure that virtually no Medicare patient paid a co-pay, deductible, or co-insurance amount (collectively referred to herein as a "co-pay") on Eylea and that physicians who prescribed and purchased the drug did not have to collect Medicare co-pays from their patients.

2. Before Regeneron began selling Eylea in late 2011, it considered a price range of $1,500 to $1,950 per injection for the drug. Ultimately, the company chose a price – $1,850 – at the higher end of that range because it knew that it could eliminate any financial burden that the higher price would impose on Medicare patients and their physicians simply by paying more to a foundation that would cover the proportionately higher Medicare co-pays for Eylea. As a marketing consultant for Regeneron advised the company in the spring of 2011, "[t]he overall financial impact considering revenue of increasing price [of Eylea] . . . is largely favorable to

Regeneron, since the revenue increase will offset the increase in the budget needs to run the [foundation co-pay] program."

3. The following year, as sales of Eylea began to ramp up, Regeneron considered how much to pay Chronic Disease Fund ("CDF"), a purportedly "independent" foundation which operated a fund that covered Medicare co-pays for macular degeneration drugs. At the time, Regeneron and Genentech, which sold Lucentis, were the leading manufacturers of macular degeneration drugs. Regeneron's senior management was only willing to pay CDF enough to cover Medicare co-pays for Eylea patients; as Regeneron's former Chief Financial Officer, Murray Goldberg, put it, Lucentis patients were "Genentech's problem." Moreover, Regeneron senior management wanted assurances that the company's payments to CDF would generate return on investment, or "ROI."

4. To satisfy senior management, Regeneron employees repeatedly contacted CDF to learn the amount of money CDF would need to cover the co-pays of Eylea patients only. They then determined the Medicare revenue that Regeneron would derive from those patients and calculated that the company would earn a return of over 400% on its payments to CDF. Over the course of 2013 and through the beginning of 2014, Regeneron paid CDF exactly what CDF said it needed to cover Medicare expenses for Eylea patients only.

5. Because the anti-kickback statute, 42 U.S.C. § 1320-7b(b), prohibits such "indirect" kickbacks to subsidize the price of a drug reimbursed by Medicare, Regeneron's conduct was illegal, and senior management knew it. During 2013, company auditors twice inquired about the information Regeneron was getting from CDF about Eylea. Both times, Regeneron management, including the company's commercial chief, Robert Terifay, lied and asserted that the company was not getting Eylea-specific data from CDF. In fact, as Terifay and

others knew, the company was getting frequent Eylea-specific reports from CDF and then using that data to correlate the company's payments to CDF with the foundation's spending on co-pays for Eylea. Regeneron's payments to CDF were not charity; rather, the company intended those payments to subsidize Eylea's high price for Medicare patients and to ensure that physicians would not have to worry about collecting co-pays on Eylea from their Medicare patients.

Jurisdiction and Venue

6. This action arises under the False Claims Act ("FCA"), as amended, 31 U.S.C. §§ 3729-33. This Court has jurisdiction over this action under 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1345 and 1367(a).

7. Venue is proper in the District of Massachusetts pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a).

8. This Court may exercise personal jurisdiction over Regeneron pursuant to 31 U.S.C. § 3732(a) and because the company transacts business in this District.

The Parties

9. Plaintiff United States, acting through the Department of Health and Human Services ("HHS"), administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.* (Medicare).

10. Defendant Regeneron is a manufacturer and seller of pharmaceutical products, including Eylea. Regeneron has its principal place of business at 777 Old Saw Mill River Road, Tarrytown, NY 10591. Regeneron conducts business nationwide.

Legal Background

The Medicare Part B Program and Co-Pays Under Medicare Part B

11. Congress established Medicare in 1965 to provide health insurance coverage for

people aged sixty-five or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 1395 *et seq*.

12. Medicare is funded by the federal government and administered by the Centers for Medicare and Medicaid Services ("CMS"), which is part of HHS.

13. Medicare Part B primarily covers outpatient medical services and physician-administered drugs, like Eylea.

14. Once beneficiaries meet their annual deductible (currently $198), Medicare Part B pays 80 percent of the cost of prescription drugs administered by a physician in an outpatient setting. 42 U.S.C. § 1395l(a)(1). Some Medicare beneficiaries purchase a supplemental insurance product, called a Medigap plan, to cover the remaining 20 percent co-pay. Others are responsible for covering that co-pay directly.

15. Congress incorporated co-pays into Medicare to give patients an incentive to choose the most cost-effective therapy. As the Department of Health and Human Services, Office of the Inspector General observed in a 1994 Special Fraud Alert, "[s]tudies have shown that if patients are required to pay even a small portion of their care, they will be better health care consumers, and select items or services because they are medically needed, rather than simply because they are free." *Available at* https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

16. When a physician administers a drug covered by Medicare Part B, the physician typically submits a claim to Medicare for the drug. Medicare then will reimburse the physician 106 percent of the average sales price of the drug, less the applicable Medicare Part B co-pay. *See* 42 U.S.C. § 1395w–3a(b). The physician is responsible for collecting the co-pay amount from the patient.

The False Claims Act

17. The FCA provides, in pertinent part, that any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

18. For purposes of the FCA, the terms "knowing" and "knowingly" mean that a person, with respect to information: (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1).

19. The FCA defines the term "claim," in pertinent part, as

> any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government--(I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded[.]

31 U.S.C. § 3729(b)(2).

20. For purposes of the FCA, the term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* at

§ 3729(b)(4).

The Anti-Kickback Statute

21. The anti-kickback statute, 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions would result in goods and services being provided that are excessively costly, medically unnecessary, of poor quality, or potentially harmful to patients. To protect the integrity of Federal health care programs from these difficult-to-detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gives rise to overutilization, poor quality of care, or patient harm. In particular, when determining what conduct to prohibit, Congress determined that the inducements at issue would "contribute significantly to the cost" of federal health care programs absent federal penalties as a deterrent. H.R. Rep. No. 95-393, at 53 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3056. First enacted in 1972, Congress strengthened the anti-kickback statute in 1977, 1987, and 2010 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93; Patient Protection and Affordable Care Act, Pub. L. No. 111-148.

22. The anti-kickback statute prohibits any person or entity from offering, making, soliciting, or accepting remuneration, in cash or in kind, directly or indirectly, to induce or reward any person for purchasing, ordering, or recommending or arranging for the purchasing or ordering of federally-funded medical goods or services:

> (b) Illegal remunerations
> * * *
> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b)(2). Violation of the anti-kickback statute also can subject the perpetrator to exclusion from participation in federal health care programs and civil monetary penalties. 42 U.S.C. § 1320a-7b(b)(2); 42 U.S.C. § 1320a-7(b)(7); 42 U.S.C. § 1320a-7a(a)(7).

23. The anti-kickback statute defines remuneration to include anything of value, including "cash" and "in-kind" payments or rebates. 42 U.S.C. § 1320a-7b(b)(2). Money and other forms of financial subsidies that can be used to pay or waive Medicare co-pays constitute remuneration under the anti-kickback statute.

24. The anti-kickback statute defines a "Federal health care program" to mean "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government," except for the health insurance program for federal employees under 5 U.S.C. §§ 8901 *et seq*. 42 U.S.C. § 1320a-7b(f). Medicare is a "Federal health care program" for purposes of the anti-kickback statute.

25. The anti-kickback statute provides that, "[w]ith respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section." 42 U.S.C. § 1320a-7b(h).

26. In 2010, Congress amended the anti-kickback statute to include language that reaffirmed prior case law and provided that any Medicare claim "that includes items or services resulting from a violation of [the anti-kickback statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g). Under this provision, claims submitted to federal health care programs that result from violations of the anti-kickback statute are *per se* false or fraudulent within the meaning of 31 U.S.C. § 3729(a). Accordingly, a person violates the False Claims Act when he or she knowingly submits, or causes to be submitted, a claim to a federal health care program that results from a violation of the anti-kickback statute.

27. Compliance with the anti-kickback statute is material to CMS's decision to pay a Medicare claim.

Factual Allegations

Background on Regeneron and Eylea

28. Leonard Schleifer founded Regeneron in 1988. For the company's first 20 years, it primarily focused on clinical research. In 2008, the Food and Drug Administration ("FDA") approved Regeneron's first commercial product, Arcalyst.

29. In November 2011, FDA approved Eylea to treat neovascular (wet) age-related macular degeneration ("AMD"), a disease that afflicts millions of elderly people around the world. Physicians administer Eylea by injection in the office. The recommended dose is 2 mg per eye once a month for the first 12 doses, and about 6 to 7 times per year thereafter. The list price of Eylea is $1,850 per dose, so the annual cost is typically well over $10,000 and the associated Medicare Part B co-pays owed by patients are well over $2,000 per year. Even patients with Medigap often face annual deductibles of several hundred dollars the first time they take Eylea each year.

30. Eylea has two principal competitors, Avastin and Lucentis, both made by Genentech. Avastin and Lucentis are chemically similar drugs, but FDA has approved Avastin to treat certain types of cancer and it comes in 4 ml and 16 ml vials, while FDA has approved Lucentis to treat various eye conditions and it comes in .5 ml vials. Because Lucentis is much more expensive than Avastin per milliliter, ophthalmologists sometimes use Avastin off-label: compounding pharmacies buy Avastin vials and divide them into smaller doses for injection into the eye, which ophthalmologists purchase. Eylea, Lucentis, and Avastin all have comparable efficacy. *See generally* National Eye Institute, *Avastin as Effective as Eylea for Treating Central Retinal Vein Occlusion* (May 9, 2017), *available at* https://www.nei.nih.gov/about/news-and-events/news/avastin-effective-eylea-treating-central-retinal-vein-occlusion; National Institutes of Health, *Avastin and Lucentis Are Equivalent in Treating Age-Related Macular Degeneration* (Apr. 30, 2012), *available at* https://www.nih.gov/news-events/news-releases/avastin-lucentis-are-equivalent-treating-age-related-macular-degeneration. When used in this manner off-label, Avastin costs approximately $55 per dose, while Lucentis costs approximately $2,000 per dose and Eylea $1,850 per dose. Nonetheless, because co-pay foundation coverage is readily available for Eylea and Lucentis but not for Avastin, Eylea and Lucentis are actually cheaper than Avastin for patients facing Medicare co-pays. On the other hand, when physicians knew that co-pay coverage was not available for Eylea or Lucentis, they often prescribed Avastin, so as not to impose large Medicare co-pays on their patients or risk being unable to collect those co-pays.

31. Although it was not Regeneron's first commercial product, Regeneron's launch of Eylea ushered in Regeneron's transition to a commercially-focused entity and its creation of a commercial organization. Eylea is now the top-selling drug in the United States for AMD.

Background on CDF

32. Michael Banigan founded CDF in 2004. In 2006, CDF began soliciting and receiving money from pharmaceutical companies and then using that money to cover co-pays for those companies' drugs.

33. Since at least 2010, CDF has operated a fund that covers Medicare co-pays for patients taking drugs for AMD. Prior to FDA's approval of Eylea, Genentech's Lucentis was the only FDA-approved therapy for AMD, and Genentech alone financed CDF's AMD fund. Once FDA approved Eylea in 2011, CDF's fund issued grants for both Lucentis and Eylea, but not Avastin.[1]

34. CDF now operates as Good Days.

35. If CDF has approved a grant for an Eylea patient, the patient's physician may submit a claim to CDF for the applicable Medicare deductible or co-pay amount each time the physician administers Eylea to that patient, and CDF then will pay that amount directly to the physician. *See* Good Days EPay Billing Guide, *available at* https://www.mygooddays.org/epay/EPay_Billing%20Guide.pdf.

The Evolution of Regeneron's Funding of CDF

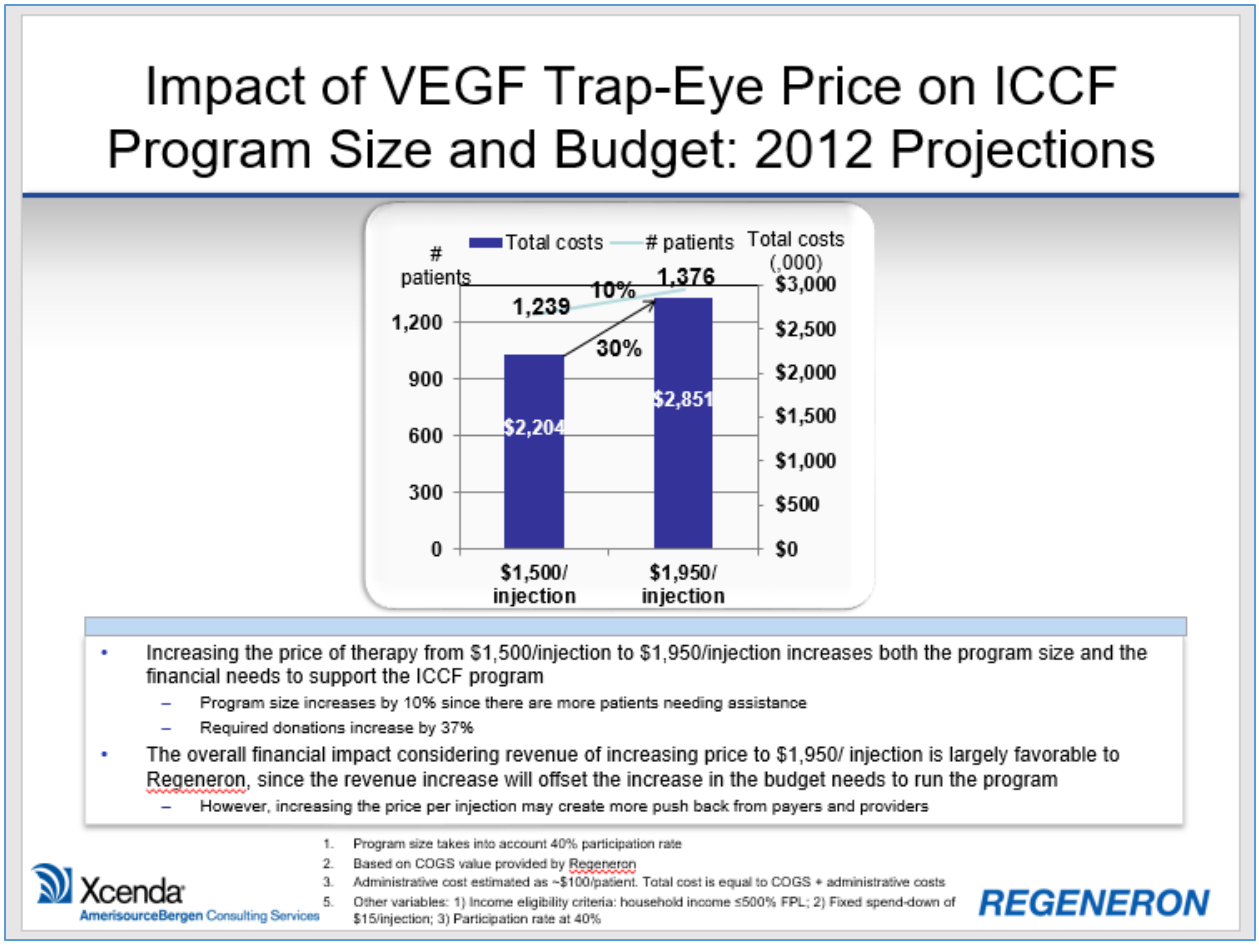
2011-12

36. Prior to the launch of Eylea, Regeneron's commercial team understood that the price of the drug would make the drug unaffordable for many people suffering from wet AMD, including Medicare beneficiaries, and that, as a result, the price could cause physicians not to prescribe the drug. Accordingly, Regeneron commissioned Xcenda, a division of

[1] CDF also operated a small fund for patients taking drugs for retinal vein occlusion ("RVO"), for which physicians also prescribe Eylea and Lucentis.

AmerisourceBergen Corporation, to analyze various matters concerning the pricing and reimbursement for Eylea including, among other things, how to price Eylea, how to structure the free drug program for Eylea, and how much money Regeneron should anticipate spending on foundation support for Eylea. In coming up with an estimate of how much Regeneron should budget for co-pay foundation funding, Xcenda began by observing that 77 percent of wet AMD patients were Medicare beneficiaries. Xcenda then estimated the proportion of those Medicare beneficiaries who would seek foundation coverage for their co-pays, estimated the amount of foundation funding each beneficiary would receive, and applied those estimates to Regeneron's Eylea sales projections. Using that methodology, Xcenda projected that Regeneron should spend just under $3 million on foundation support in 2012. (A copy of the slide presentation with Xcenda's findings is attached as Exhibit 1. Xcenda used the term "ICCF" to refer to co-pay foundations.)

37. At the time of Xcenda's analysis, Regeneron was considering a price of $1,500 per Eylea injection. In its analysis, Xcenda noted that Regeneron could increase that price to $1,950 per injection, but that the higher price would necessitate Regeneron increasing its foundation funding by 43%. Notwithstanding the increased cost of foundation funding with the higher price, Xcenda advised that "[t]he overall financial impact considering revenue of increasing price to $1,950/injection is largely favorable to Regeneron, since the revenue increase will offset the increase in the budget needs to run the program." An image of this slide is below:



As noted above, Regeneron ultimately settled on a price of $1,850 per Eylea injection, or 23 percent higher than the price the company earlier had considered.

38. Xcenda's analysis further noted that Regeneron could provide free Eylea to Medicare patients who could not afford it, but Xcenda recommended that Regeneron instead refer those patients to a co-pay foundation. Xcenda explained that patients who received free Eylea would not generate revenue for Regeneron, whereas Eylea patients who received Medicare co-pay coverage from a foundation would generate revenue for Regeneron from the resulting Medicare claims. Regeneron followed this advice, too, and offered free Eylea only to patients without insurance coverage for Eylea; the company barred Medicare patients from its free drug program even if they could not afford the co-pays for Eylea.

39. Regeneron management understood from the outset that, absent the availability of Medicare co-pay coverage for Eylea, physicians would prescribe and purchase Avastin rather than Eylea. Thus, Cynthia Sherman, a Senior Director for Reimbursement at Regneron testified as follows:

> Q: But people understood that if co-pay assistance was not available for Eylea or Lucentis patients, that patients with wet AMD would end up on Avastin?
>
> A: Yeah, that's why they wanted to have a managed care co-pay program.

40. Notwithstanding Xcenda's projection that Regeneron should spend nearly $3 million on foundation support in 2012, Regeneron's management was initially skeptical of how payments to foundations could generate revenue for Regeneron. Moreover, Regeneron's management knew that CDF paid Lucentis patients' co-pays in addition to Eylea patients' co-pays. Without more information from CDF, Regeneron could not determine whether its payments to CDF would cover Eylea co-pays or Lucentis co-pays. Accordingly, until CDF provided more information about the projected aggregate co-pays for Eylea, Regeneron paid CDF far less than what Xcenda recommended.

41. Specifically, Regeneron only paid CDF $125,000 at the end of 2011 (FDA did not approve Eylea for treatment of wet AMD until November 28, 2011) and $600,000 in 2012. In testimony, Sherman explained that Regeneron senior management did "not provide a lot of money the first year because you just didn't know how many -- what the uptake of Eylea would be, and Regeneron did not want to pay for Lucentis's co-pay."

42. As it happened, Eylea's sales performance in 2012 greatly exceeded Regeneron's pre-launch expectations. This caused Regeneron to consider paying CDF more, but Regeneron was not willing to do so absent proof that CDF needed the money to fund Eylea co-pays (and not

Lucentis co-pays).

43. On July 9, 2012, Robert Krukowski, Regeneron's Senior Manager for Reimbursement & Managed Markets Marketing, sent an e-mail to his direct report, William Daniels, asking if Daniels had spoken to Clorinda Walley, CDF's Executive Director, about "upping our contributions for 2013." Krukowski added that "[w]e probably should up our overall contribution to CDF given our [*i.e.*, Eylea's] performance but it is going to be hard to just pick a number." (A copy of this e-mail is attached as Exhibit 2.)

44. On July 23, 2012, Daniels sent an e-mail to Walley advising that he had a meeting scheduled "to review our budget planning for 2013," and that he was "going to need to justify my request for our 2013 donation." Accordingly, Daniels asked if he and Walley could "meet prior to then to review the numbers." (A copy of this e-mail is attached as Exhibit 3.)

45. In a response the next day, Walley provided Daniels with a spreadsheet entitled "Regeneron Projections 2013." Daniels understood that the spreadsheet showed how many Eylea patients were in the fund, how many Eylea patients CDF projected to be in the fund in 2013, and how much money CDF would need to cover co-pays for those patients. The spreadsheet stated that CDF's "Total Projected Funding Needed" from Regeneron was just over $40 million. Daniels promptly forwarded Walley's e-mail to his boss, Krukowski, with a cover e-mail stating: "See projections for next year. She is stating that her 2013 projection is pretty much our 2012 actuals." (A copy of this e-mail chain, including Walley's spreadsheet, is attached as Exhibit 4.)

46. On August 8, 2012, Daniels sent Krukowski an e-mail in preparation for a budget meeting with Terifay, who was then Regeneron's Vice President, Commercial, and later became the company's Executive Vice President, Commercial. At the time, Daniels believed that

Regeneron senior management was unlikely to approve a $40 million budget for CDF in 2013. In his e-mail, Daniels tried to use Eylea's market share to come up with a lower estimate of the amount CDF would need to cover Eylea patients' Medicare expenses in 2013. Whereas Walley had projected that CDF would need about $17 million just to cover "rollover patients" [*i.e.*, renewals of grants that CDF had given Eylea patients in 2012], Daniels' market share approach yielded an estimate of about $5.6 million for those patients. Daniels further projected that the "ROI" to Regeneron from funding these patients would be nearly $25 million, or a return of more than 4 to 1. On August 14, 2012, Daniels replied to his own August 8 e-mail with estimates of the amounts Regeneron would have to pay CDF to cover *new* Eylea patients in 2013. His estimates for those patients ranged from about $11.5 million to over $19 million. (A copy of this e-mail chain is attached as Exhibit 5.)

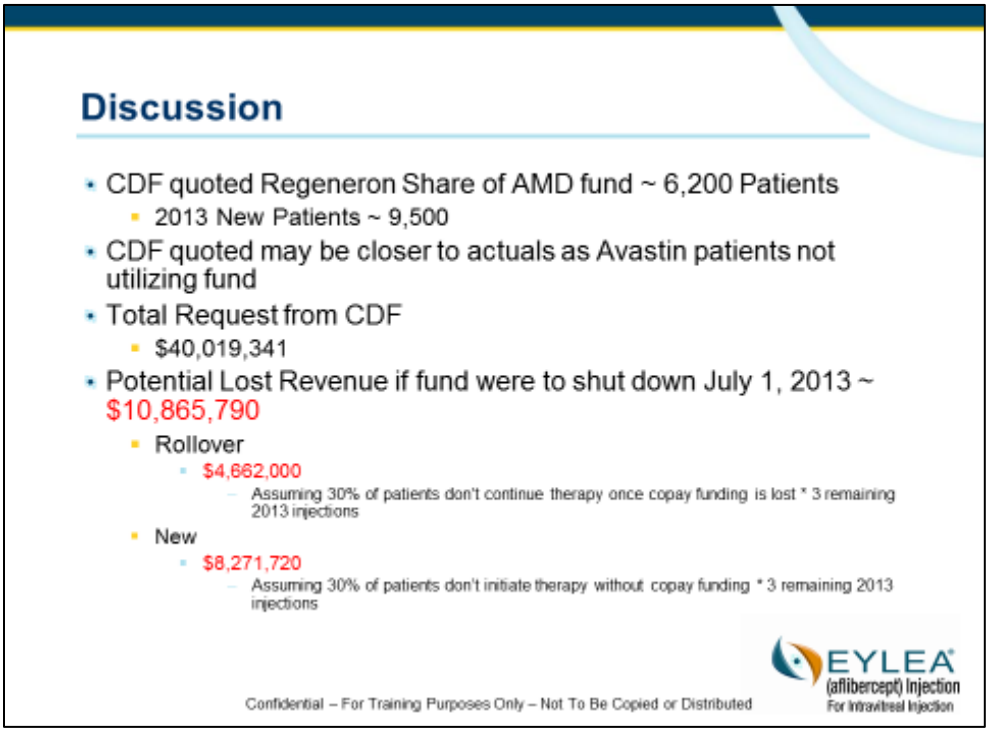
47. Later on August 14, 2012, Krukowski sent out an invitation for a meeting on August 20, 2012, to discuss "Foundation Funding considerations." The invitees included Terifay, Daniels, and Stephen Dressel, a Regeneron financial analyst. In the invitation, Krukowski explained what "we would like to bring you up to speed on our current activity through CDF this year and gain consensus on our foundation funding strategy (ROI, risks, considerations) for 2013." (A copy of this invitation is attached as Exhibit 6.)

48. On August 16, 2012, in anticipation of a pre-meeting that day to discuss "CDF Funding," Daniels circulated a comparison of his and Walley's projections. Daniels included a projection of millions of dollars of "Potential Lost Sales" if Regeneron did not pay CDF enough to cover the Medicare expenses of potential new Eylea patients who would seek funding from CDF in 2013. The recipients of Daniels' e-mail included Krukowski and Robert Davis, who reported directly to Terifay and was Regeneron's Executive Director and Head of Trade,

Reimbursement & Managed Markets. (A copy of this e-mail is attached as Exhibit 7.)

49. The meeting scheduled with Terifay for August 20, 2012, was rescheduled for October 8, 2012.

50. On August 27, 2012, Daniels sent Krukowski and Cathy Casey, Regeneron's Senior Director for Reimbursement Strategy, a slide presentation entitled "CDF 2013." According to Daniels, an objective of the presentation was to "Ensure Sr. Management is aware of the CDF funding strategy and implications to the EYLEA franchise if CDF's funding for AMD/RVO were to run out in 2013." Daniels noted that "CDF management has communicated that for 2013, if every donor doesn't cover their market share the fund will be closed." He further reported the following:



(A copy of this presentation is attached as Exhibit 8.)

51. On October 4, 2012, in anticipation of the upcoming meeting with Terifay, Daniels sent an updated version of his presentation slides to Dressel, the financial analyst. (A

copy of this presentation is attached as Exhibit 9.)

52. At the meeting on October 8, 2012, Terifay rejected Daniels' suggestion and indicated that, subject to further discussions with Goldberg, the CFO, Regeneron would pay CDF just $2.5 million in 2013. Daniels subsequently conveyed to Walley that Regeneron would pay CDF $2.5 million in January 2013.

53. On December 19, 2012, Walley sent Daniels an e-mail warning that a payment of only $2.5 million would not enable CDF's AMD fund to remain open past early 2013. With her e-mail, Walley attached a revised projection showing that the AMD fund would need just under $25 million to cover co-pays for Eylea patients in 2013. (A copy of this e-mail is attached as Exhibit 10.)

54. Later on December 19, 2012, Krukowski sent an e-mail to his colleague, Casey, about CDF funding. In his e-mail, Krukowski observed that CDF was "processing re-enrollments for next year and we have 6800 patients being re-enrolled." Krukowski added:

> They [CDF] have provided us more information on Gene[ntech] funding and we really need to make everyone aware of the risks and what is our true commitment. Apparently Steve [Dressel] and Bob T[erifay] agreed to fund CDF for $10 Mil next year but thought it would be better to hid[e] it from us. I feel confident that we still have an issue at $10 mil based up[on] what CDF is stating and has shared with us.

(A copy of this e-mail is attached as Exhibit 11.)

2013

55. On January 3, 2013, Daniels and Krukowski met with Terifay, Davis, and Dressel to discuss CDF. The meeting invitation noted that Daniels "has had a follow [on conversation with] CDF and new information to discuss regarding the other Donor[']s commitments and our current roll over patients." (A copy of this meeting invitation is attached as Exhibit 12.) After the meeting, Krukowski sent Casey and Davis an e-mail reiterating that "the additional $2.5 mil

we were planning on funding in Q1 was not enough based up[on] the current number of EYLEA patients CDF has already rolled over and enrolled for 2013." Krukowski noted that Daniels "did an excellent job presenting the attached analysis [Daniels' comparison of Walley's original Regeneron projection and his own] on why we need to up our funding in Q1 significantly and made Bob T[erifay] aware that we potentially need ~$25Mil to adequately fund our patient responsibility for 2013." Krukowski added that Terifay "wanted to keep a copy of this to review with 'the boys', I am assuming Len [Schleifer] and Murray [Goldberg] to see if we can get $10mil to fund for Q1." (A copy of this e-mail is attached as Exhibit 13.)

56. The next day, Christopher Fenimore, Regeneron's Vice President of Financial Planning, sent two e-mails to Dressel and others concerning CDF. In the first e-mail, Fenimore asked Dressel "to walk us through with Bob [Terifay] the economics of how much we contributed last year vs. [Genentech], how much got paid out to Lucentis vs. EYLEA patients last year, and based on this info what we think we'll need to do this year to keep the fund solvent." In the second e-mail, Fenimore reported that "Bob [Terifay] just walked me through the logic…We agreed to put $25MM in the plan." (A copy of these e-mails is attached as Exhibit 14.) In other words, Regeneron planned to pay CDF almost exactly what CDF said it needed at that point to cover co-pays for Eylea patients.

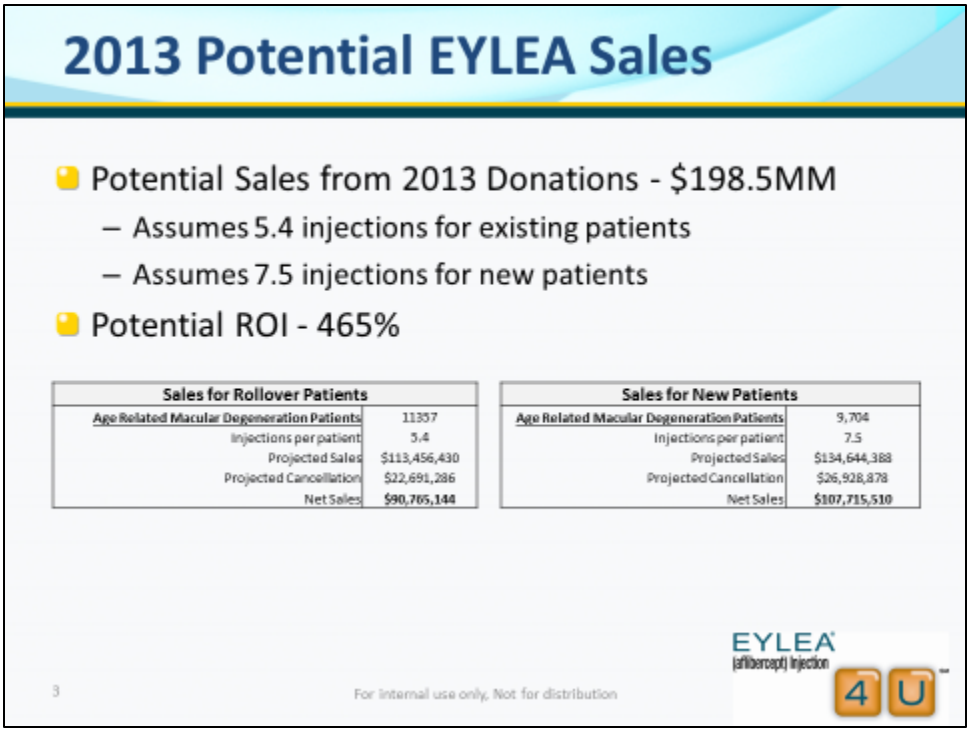
57. Shortly thereafter, Krukowski sent Daniels an e-mail reporting that Dressel had told him that Terifay and Fenimore had "agreed to $8mil for Q1!" (A copy of this e-mail is attached as Exhibit 15.) By early February, however, Regeneron still had not paid CDF anything in 2013. On February 6, 2013, Dressel sent Daniels an e-mail asking for another copy of Daniels' comparison of Walley's original Regeneron projection with his own. Dressel explained that he was "[c]hecking with Bob [Terifay]" and that the analysis "will need to go to Murray

[Goldberg] and Len [Schleifer]." (A copy of this e-mail is attached as Exhibit 16.)

58. On or about February 13, 2013, Regeneron paid CDF $5 million. On or about May 1, 2013, Regeneron paid CDF $7.5 million. Thus, in the first half of the 2013, Regeneron paid CDF almost exactly half of what CDF had said it needed to cover co-pays for Eylea patients in all of 2013.

59. On June 18, 2013, Walley sent Daniels an e-mail with an updated version of her "Regeneron Projections 2013" spreadsheet. The spreadsheet showed that CDF would need more money – nearly $35 million – to cover co-pays for Eylea patients for the full year 2013. (A copy of this e-mail is attached as Exhibit 17.)

60. On June 24, 2013, Daniels sent Krukowski a set of "CDF Slides" he had prepared to explain why Regeneron should pay CDF $35 million, rather than $25 million, in 2013. At the outset, using Eylea-specific information he had obtained from Walley, Daniels reported that "CDF has paid out $32.6MM through 6/3/13" and that CDF's "2013 renewals" for Eylea patients accounted for "~41% of Fund." Daniels then presented the "ROI" Regeneron could expect from paying CDF $35 million in 2013:



2013 Potential EYLEA Sales

- Potential Sales from 2013 Donations - $198.5MM
  - Assumes 5.4 injections for existing patients
  - Assumes 7.5 injections for new patients
- Potential ROI - 465%

Sales for Rollover Patients	
Age Related Macular Degeneration Patients	11357
Injections per patient	5.4
Projected Sales	$113,456,430
Projected Cancellation	$22,691,286
Net Sales	$90,765,144

Sales for New Patients	
Age Related Macular Degeneration Patients	9,704
Injections per patient	7.5
Projected Sales	$134,644,388
Projected Cancellation	$26,928,878
Net Sales	$107,715,510

(A copy of Daniels' slides is attached as Exhibit 18.)

61. On June 26, 2013, Daniels presented these slides to Fenimore and Dressel. After the meeting, Fenimore sent the slides to Goldberg, the CFO, with a cover note that "[t]his makes sense to me." (A copy of Fenimore's e-mail is attached as Exhibit 19.) Shortly thereafter, Dressel sent Daniels an e-mail complimenting him on his presentation to Fenimore and reporting that Regeneron now was planning was to make additional payments to CDF so that CDF would receive the full $35 million it said it needed from Regeneron to cover co-pays for Eylea patients in 2013. (A copy of the e-mail chain reflecting this plan is attached as Exhibit 20.)

62. On July 9, 2013, Fenimore sent Goldberg two e-mails confirming the updated funding plan for CDF. (A copy of Fenimore's e-mails is attached as Exhibit 21.)

63. On or about August 21, 2013, Regeneron paid CDF $7.5 million. On or about September 25, 2013, Regeneron paid CDF $10 million. On or about October 1, 2013, Regeneron paid CDF $5 million. Thus, in 2013, Regeneron paid CDF at total of $35 million, which is

almost exactly what CDF had told Regeneron it needed to cover co-pays for Eylea patients in 2013.

January 2014

64. On January 3, 2014, Krukowski sent Daniels an e-mail asking "Have you got anywhere with Clorinda [Walley] at CDF? I would like to bring this up on the call [with Regeneron management] at the end as well and tell them what you are trying to obtain from her." In response, Daniels reported that he had just spoken with Walley and that he "should have her Q1 request by [end of day]." (A copy of this e-mail exchange is attached as Exhibit 22.)

65. Later on January 3, 2014, Walley sent Daniels a projection of CDF's needs for Eylea patients in the first quarter of 2014 and for the full year 2014, and Daniels forwarded it to his managers. (A copy of this e-mail chain is attached as Exhibit 23.) Walley's summary of her request to Regeneron for the first quarter of 2014 is below:

Please find attached an updated AMD projection need for 2014 which includes CDF's need to facilitate assistance for renewal and new patients in the 1st quarter. I have summarized below.

2014 Renewals	$ 29,434,885
2013 Roll-Over	$ 9,500,000
Total 2014 ReEnrollment Need	$ 19,934,885
Total 2014 1st Qtr Need	$ 5,495,226
Sum of Need Existing/New 1st Qtr 2014	$ 25,430,111

According to Walley's summary, CDF expected to need (1) about $29.5 million in 2014 to renew grants for Eylea patients who had received grants in 2013, and (2) about $5.5 million to cover 2014 grants for new patients who would start on Eylea in the first quarter of 2014. At the same time, according to Walley's summary, CDF intended to credit Regeneron $9.5 million for amounts that CDF had not ended up paying out on grants in 2013. Thus, CDF's total ask to

Regeneron for the first quarter of 2014 was approximately $25.5 million. When later asked about this request, Daniels gave the following sworn testimony:

Q: Did you understand that that request was to cover costs for Eylea only?

A: Yes.

66. On January 6, 2014, Daniels sent an e-mail to Terifay, Dressel, and others recommending that Regeneron pay CDF $25.5 million in the first quarter of 2014, in two equal installments of $12.75 million each. (A copy of this e-mail is attached as Exhibit 24.)

67. On January 9, 2014, Krukowski and Daniels learned that, according to an e-mail from a Regeneron sales representative, CDF "was out of funds" and that, as a result, a large retina clinic was "putting patients only on Avastin." (A copy of this e-mail is attached as Exhibit 25.)

68. A day later, on January 10, 2014, Davis sent Daniels and Krukowski an e-mail notifying them that "the $12.75 million amount was decided by Len [Schleifer] and Bob Landry [Goldberg's successor as CFO]." (A copy of this e-mail is attached as Exhibit 26.)

69. On or about January 15, 2014, Regeneron paid CDF $12.75 million.

70. After early 2014, the scrutiny of CDF and other co-pay foundations intensified, and CDF and Regeneron became more circumspect in their written communications and patterns with respect to funding requests and payments. Nonetheless, by that time, Regeneron understood from CDF that CDF was using Regeneron's money to ensure that physicians did not need to consider the impact of Medicare co-pays when deciding to purchase and prescribe Eylea.

Regeneron Knew That Its Conduct Was Wrong

71. Regeneron knew that it should not use CDF as a pass-through vehicle to subsidize Medicare co-pays for Eylea, and it knew that it should not be using Eylea-specific data from

CDF to correlate its payments to CDF with CDF's expenditures on Medicare co-pays for Eylea.

72. Regeneron had this knowledge before it started funding CDF. Thus, for example, in an e-mail about "Copay Foundation" on August 9, 2011, Daniels's predecessor, Cynthia Sherman, advised Terifay, Dressel, and Davis that "we cannot get a breakdown of our spend by EYLEA users." (A copy of this e-mail is attached as Exhibit 27.) In testimony, Sherman elaborated on the warnings she gave to her superiors at Regeneron:

> Q: Okay. A moment ago you're talking about rules of the road with respect to Medicare foundations and that you couldn't designate your donations specifically for your drug?
>
> A: Right.
>
> Q: Right. Did you communicate that to Bob Davis and Bob Terifay?
>
> A: Yes.
>
> Q: And how about the fact that you couldn't get actual utilization data from the foundation? Did you also communicate that to Davis and Terifay?
>
> A: Absolutely.
>
> Q: Did you get any pushback from that?
>
> A: Yes.
>
> Q: What was the pushback?
>
> A: They just wanted to know why if we're going to give money, why we can't have a more detailed, you know, overview of who they're providing our financial assistance to. And I said the only time you can do that is if you have something in-house and we can't -- for Medicare we can't do it in-house. It would only be commercial.

73. In October 2012, after the meeting where Daniels reported that CDF was funding approximately 6,200 Eylea patients, Davis warned Krukowski and Daniels that Regeneron should not be getting or using Eylea-specific data from CDF.

74. On December 5, 2012, Daniels sent Krukowski a copy of a Special Advisory

Bulletin that the Office of Inspector General to the Department of Health and Human Services ("HHS-OIG") had issued in November 2005. *See* HHS-OIG, Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005). In that bulletin, HHS-OIG advised that, notwithstanding the facial applicability of the anti-kickback statute to payments by pharmaceutical manufacturers to patients via foundations, "pharmaceutical manufacturers can donate to bona fide independent charity PAPs, provided appropriate safeguards exist." *Id.* at 70625. The bulletin spelled out these "safeguards," including that a foundation "must not function as a conduit for payments by the pharmaceutical manufacturer to patients," and that a pharmaceutical manufacturer should not "solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products." *Id.* at 70626, 70627.

75. In a demonstration of their knowledge that they should not be using Eylea-specific data from CDF, Regeneron executives repeatedly lied to the company's internal auditors in 2013 when the auditors posed questions about how the company was determining the amounts it was paying CDF.

76. In February 2013, Regeneron's Vice President of Internal Audit, John Calabro, and its Manager of Internal Audit, Thibaux Corbin de Mangoux, were conducting an audit that that focused primarily on Regeneron's financial assistance program for patients with commercial insurance. As part of this audit, the audit team began asking questions about Regeneron's relationship with CDF.

77. On February 20, 2013, Corbin sent Daniels an e-mail seeking information about Regeneron's relationship with CDF. Corbin asked Daniels to "provide us some detail around the

rationale for the amount paid," including any "analysis" used to determine that amount. Corbin also asked whether Regeneron received any "feedback reports . . . on how money given by Regeneron is actually being spent." Daniels forwarded Corbin's request to Krukowski and Davis, with the following cover e-mail (highlighting added):

From: William Daniels
Sent: Friday, February 22, 2013 11:00 AM
To: Robert Davis
Cc: Robert Krukowski
Subject: FW: Co-pay referrals to non-profit organizations - Follow Up Questions

Bob,
Please see below. I am not really comfortable providing the documentation he is requesting. I wanted to know your thoughts.

Davis subsequently forwarded the e-mail chain to Terifay, who responded: "I will handle." (A copy of this e-mail chain is attached as Exhibit 28.)

78. Of course, by that time, as Terifay, Davis, Krukowski, and Daniels well knew, Regeneron already had received data from CDF showing how many Eylea patients CDF was funding and how much money CDF projected it would need to cover Eylea patients in 2013, and the company had used that information to determine how much it planned to pay CDF in 2013. But the commercial team hid all of this from the auditors, because they knew it reflected wrongful conduct.

79. On February 23, 2013, Terifay responded to Calabro, Corbin's boss. In his e-mail, Terifay recognized that "[p]harmaceutical companies cannot provide reimbursement assistance of any kind to patients covered in any way by a government insurance program," and that, when pharmaceutical companies support foundations like CDF, "[d]onors have no rights to information of any sort on disposition of funds." Terifay further stated that: "We cannot ask for any information from the CDF. We gave a charitable donation."

80. Terifay's February 23 e-mail to Calabro also forwarded Daniels' earlier e-mail

about Corbin's questions, except that Terifay had altered Daniels' e-mail to read as follows (highlighting added):

From: William Daniels
Sent: Friday, February 22, 2013 11:00 AM
To: Robert Davis
Cc: Robert Krukowski
Subject: FW: Co-pay referrals to non-profit organizations - Follow Up Questions

Bob,
Please see below. I am not really comfortable asking for the documentation he is requesting. I wanted to know your thoughts.

Specifically, Terifay had changed Daniels statement that he was "not really comfortable *providing* the documentation he is requesting" to a statement that Daniels was "not really comfortable *asking for* the documentation he is requesting." In other words, knowing that Regeneron should not be receiving or using Eylea-specific data from CDF, Terifay altered Daniels' e-mail to convey the false impression that the Regeneron commercial team was not already receiving and using that data, and that Regeneron would have had to ask CDF to get it. (A copy of this e-mail chain, with the altered e-mail, is attached as Exhibit 29.)

81. Terifay's deceit ended the audit team's inquiry about CDF in February 2013.

82. In November 2013, after some negative media reports concerning CDF, the Regeneron internal audit team revisited the same issue, and Terifay – this time in open collaboration with Davis, Krukowski and Daniels – deceived the audit team again.

83. On Friday, November 22, 2013, the auditors met with Davis, Krukowski, and Casey.

84. The following Monday, November 25, 2013, Calabro sent an e-mail to the meeting participants seeking to confirm, among other things, that Daniels "has not had any conversations with CDF concerning product level data." Calabro also asked for "a copy . . . of the monthly report of aggregate data we receive from CDF." Krukowski then forwarded

Calabro's e-mail to Daniels. (A copy of this e-mail chain is attached as Exhibit 30.) Calabro's e-mail indicated that, during the November 22 meeting, Krukowski and the other members of the Regeneron commercial team had misled the auditors in at least two ways. First, Calabro apparently understood from the meeting that Daniels had not been having "conversations with CDF concerning product level data," but Davis, Krukowki, and Casey knew that Daniels had been having such conversations." Second, Calabro apparently understood from the meeting that the full extent of CDF's data-sharing with Regeneron was a "monthly report of aggregate data" for CDF's entire AMD fund. Because such reports would not have broken down CDF's spending between Eylea and Lucentis patients, they would not have been useful to Regeneron in figuring out the amounts it needed to pay CDF to cover Eylea patients. In fact, Regeneron had received only one such report, in February 2012, and had not received any monthly reports of aggregate data from CDF in the following 20 months. Instead, as the members of the commercial team knew, CDF had been supporting its funding requests to Regeneron with spreadsheets showing the number of Eylea patients in the AMD fund and the amounts CDF needed to cover the Medicare co-pays just for those Eylea patients.

85. To continue the deception, Daniels sent an e-mail to Walley that same day asking her to send "a copy of the monthly CDF activity report." (A copy of this e-mail is attached as Exhibit 31.) On December 3, 2013, having obtained such a report from Walley, Daniels forwarded it to Calabro, the senior auditor. (A copy of this e-mail is attached as Exhibit 32.) In doing so, Daniels did not disclose to Calabro that he had only once before received such a "monthly" report of aggregate data from CDF or that he had repeatedly received, and used, different, Eylea-specific data from CDF.

86. On December 4, 2013, after Daniels provided him with the example of the

"monthly" report of aggregate data, Calabro sent an e-mail to Daniels, with copies to Davis, Krukowski, and Casey, asking:

- Do you receive any other reports or data in emails from CDF? If so, please provide
- How does CDF make a request for additional funding? Is it verbal or by email? How do they justify it? Please provide any documentation you might have regarding such requests.

Davis forwarded Calabro's questions to Terifay, with a subject line reading "HOW SHOULD [WE] ANSWER SECOND QUESTION FROM [CALABRO]." In response, Terifay posited: "Isn't the answer that she estimates what she needs for the year verbally and then we divide across the year when we can afford it." Terifay knew this "answer" was false, and Davis was not comfortable with it. Nonetheless, Davis forwarded it to Daniels and Krukowski. (A copy of this e-mail chain is attached as Exhibit 33.)

87. On December 5, 2013, Krukowski followed up with Daniels, telling him: "Bil, you received the answer from Bob [Terifay] yesterday so please make sure you respond to John [Calabro] tonight." (A copy of this e-mail is attached as Exhibit 34.) Shortly thereafter, Daniels followed this instruction, sending Calabro the following e-mail:

John,
No I don't receive any other reports or data
My contact estimates what she needs for the year verbally and then we divide across the year when we can afford it. If she is running low, she calls and indicates what more she needs.

(A copy of this e-mail is attached as Exhibit 35.) Daniels provided the following testimony concerning this e-mail:

Q: In that email, did you write, "No, I don't receive any other reports or data."

A: Yes, I did.

Q: Was that true?

A: No, it was not.

Q: Why did you say that if it wasn't true?

A: I was told to.

Q: And then in the rest of the answer, did you write, "My contact estimates what she needs for the year verbally, and then we divide it across the year when we can afford it. If she is running low, she calls and indicates what more she needs."

A: Yes.

Q: And in doing so, you just conveyed Mr. Terifay's answer which you consider incomplete, correct?

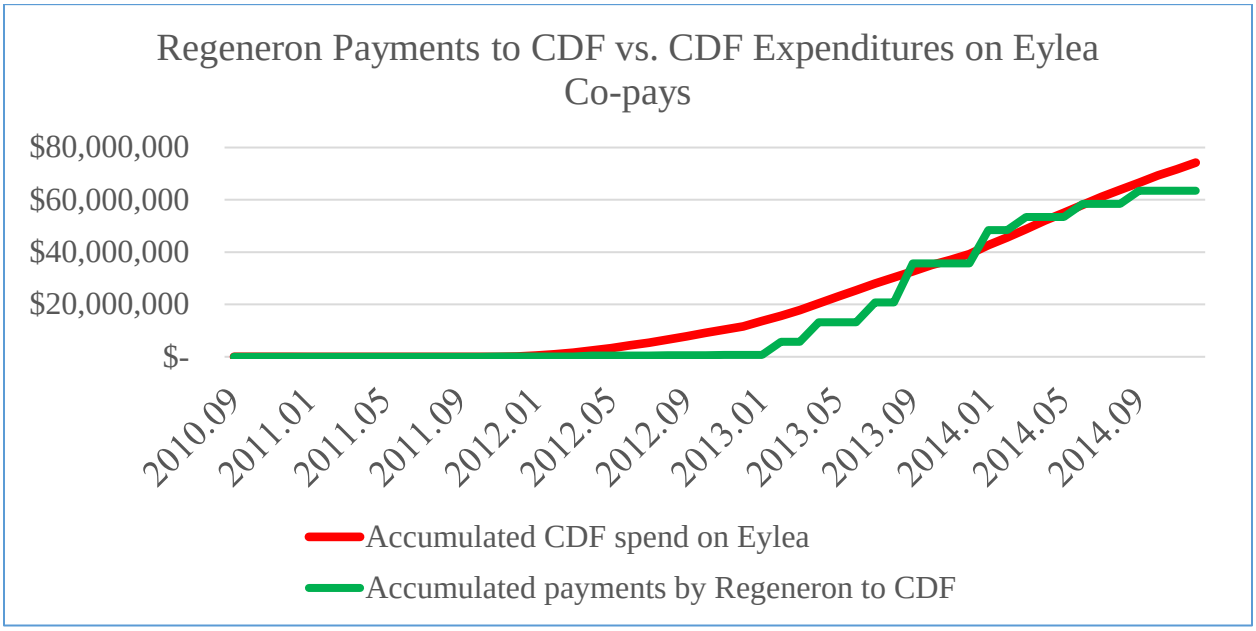
A: Yes.

88. On December 6, 2013, Calabro responded with follow-up questions to Daniels, with copies to Davis, Krukowski, and Casey: "When [Walley] makes a request for funding, how does she justify it? Can you send me an example email?" Daniels then proposed to Davis that he could tell Calabro that Walley "does provide a projection of the # of patients and the[] correlating dollars," but Davis did not give approval to send this message. (A copy of this e-mail chain is attached as Exhibit 36.) Rather, Davis himself responded to Calabro, copying Krukowski, Daniels, and Casey, with a four word answer: "It is all verbal." (A copy of this e-mail is attached as Exhibit 37.) This statement was false. In fact, as Davis, Krukowski, Daniels, and Casey all knew, Walley supported her requests with written spreadsheets; the justifications for the requests were not "all verbal."

89. Terifay, the sixth most senior executive at Regeneron, profited personally from Regeneron's kickbacks through CDF and the Eylea sales that those kickbacks generated. In 2013 and 2014, he earned over $16 million at Regeneron. After the government's investigation began, Terifay retired from Regeneron. The company never took any disciplinary action against him.

CDF'S Spending on Eylea Closely Tracked Regeneron's Payments to CDF

90. As the graph below demonstrates, Regeneron's payments to CDF (green line) correlated very closely to CDF's spend on funding for Eylea patients (red line) during the period from late 2011 through late 2014.



By 2013, the lines overlap. Thus, consistent with Regeneron's intent, CDF's AMD fund effectively functioned as a conduit for money from Regeneron to physicians who prescribed and purchased Eylea for their Medicare patients.

Regeneron's Conduct Caused the Submission of False Claims

91. Regeneron's conduct caused the submission of false claims to Medicare as a result of its violations of the anti-kickback statute.

I. Compliance with the Anti-Kickback Statute Is a Condition of Payment under Medicare Part B.

92. Medicare enters into provider agreements with providers and suppliers to establish their eligibility to participate in the program. In order to be eligible for payment under the program, physicians must certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me. . . . The Medicare laws, regulations, and program instructions are available through the Medicare Administrative Contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b) (section 1128B(b) of the Social Security Act) and the Physician Self-Referral Law (Stark Law), 42 U.S.C. section 1395nn (section 1877 of the Social Security Act)).

CMS Form 855I.

II. Regeneron's Violations Were Material to Payment Decisions.

93. Congress reaffirmed the centrality of the anti-kickback statute to the claims payment decision in amending the anti-kickback statute to provide that any Medicare claim "that includes items or services resulting from a violation of [the anti-kickback statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g).

94. Entities submitting claims to Medicare are subject to mandatory exclusion from Medicare by HHS-OIG if criminally convicted of an anti-kickback statute violation, *see, e.g.*, 42 U.S.C. § 1320a–7(a)(1), and subject to permissive exclusion if HHS-OIG determines that the entity "has committed an act" described in the anti-kickback statute, 42 U.S.C. § 1320a–7(b)(7).

95. The United States regularly enforces the anti-kickback statute and pursues False Claims Act liability based on underlying violations of the anti-kickback statute. In particular, it has pursued matters against drug companies like Regeneron for conduct like that alleged here.

96. The conduct by Regeneron undermined the core concerns of the anti-kickback statute — in particular, preventing excessive costs to Medicare resulting from illegal co-pay subsidies that facilitate high drug costs and push the financial burden of those costs to Medicare and the American taxpayer.

97. Regeneron's conduct was sustained and systemic. It involved thousands of claims submitted to Medicare.

III. Sample False Eylea Claims

98. Through the scheme described above, Regeneron provided illegal co-pay subsidies to induce thousands of Medicare-reimbursed purchases of Eylea, resulting in tens of millions of dollars of false claims to Medicare.

99. When Regeneron used CDF as a conduit to pay illegal Eylea co-pay subsidies, physicians used those subsidies to cover Medicare patients' co-pay obligations for the drug, and the physicians submitted associated claims to Medicare for the drug.

100. Medicare data shows these claims. The Medicare program generally used the Healthcare Common Procedural Coding System ("HCPCS") to reimburse for drugs. The HCPCS utilizes 5-digit alphanumeric codes to identify medical products and supplies. The HCPCS codes for Eylea are J0178 and Q2046.

101. The table below includes representative examples of false claims to Medicare for Eylea prescriptions that resulted from Regeneron's illegal co-pay subsidies via CDF:

Patient Initials	State of Residence	Date of Service	Product	Procedure Code	Amount Medicare Paid	Co-Pay Amount	Amount CDF Paid
MA	Mass.	4/4/2013	EYLEA	J0178	$1,537.42	$392.20	$392.20
RA	Mass.	5/9/2013	EYLEA	J0178	$1,537.42	$392.20	$392.20
BT	Mass.	5/22/2013	EYLEA	J0178	$1,537.42	$392.20	$392.20
RA	Mass.	6/17/2013	EYLEA	J0178	$1,537.42	$392.20	$392.20
RA	Mass.	9/17/2013	EYLEA	J0178	$1,537.42	$392.20	$392.20

Patient Initials	State of Residence	Date of Service	Product	Procedure Code	Amount Medicare Paid	Co-Pay Amount	Amount CDF Paid
GM	Mass.	10/28/2013	EYLEA	J0178	$1,537.42	$392.20	$392.20
DS	Mass.	11/22/2013	EYLEA	J0178	$1,537.42	$392.20	$392.20
RA	Mass.	11/25/2013	EYLEA	J0178	$1,537.42	$392.20	$392.20
RA	Mass.	1/16/2014	EYLEA	J0178	$1,511.81	$385.66	$392.20
RP	Mass.	2/28/2014	EYLEA	J0178	$1,537.42	$392.20	$392.20
FA	Mass.	3/6/2014	EYLEA	J0178	$1,537.42	$392.20	$392.20

COUNT I
(False Claims Act: Presentation Of False Claims)
(31 U.S.C. § 3729(a)(1)(A) (2009), formerly 31 U.S.C. § 3729(a)(1))

102. The United States re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein. By virtue of the acts described above, Regeneron knowingly presented or caused to be presented materially false or fraudulent claims for payment or approval to Medicare in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A) (2009), formerly 31 U.S.C. § 3729(a)(1); that is, Regeneron knowingly made or presented, or caused to be made or presented, to the United States claims for payment for Eylea that were tainted by illegal kickbacks.

103. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of Regeneron's conduct.

104. By reason of the foregoing, the United States has been damaged in an amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false or fraudulent claim.

COUNT II
(False Claims Act: False Records Material To A False Or Fraudulent Claim)
(31 U.S.C. § 3729(a)(1)(B) (2009), formerly 31 U.S.C. § 3729(a)(2))

105. The United States re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

106. By virtue of the acts described above, Regeneron knowingly made, used, or caused to be made or used, false records or statements, namely, false claims, false statements in Medicare Part B claims, and false statements about compliance with the anti-kickback statute, all of which were material to false or fraudulent claims for Eylea that were submitted to the United States, paid and approved by the Medicare program, and tainted by illegal kickbacks, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B) (2009), formerly 31 U.S.C. § 3729(a)(2).

107. Payment of the false or fraudulent claims was a reasonable and foreseeable consequence of Regeneron's statements and actions.

108. By reason of the false or fraudulent records or statements, the United States has been damaged in an amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false record or statement.

COUNT III
(Unjust Enrichment)

109. The United States re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

110. The United States claims the recovery of all monies by which Regeneron has been unjustly enriched, including profits Regeneron earned because of illegal inducements Regeneron paid to Medicare patients via CDF.

111. By obtaining monies as a result of its violations of federal and state law, Regeneron was unjustly enriched, and is liable to account and pay such amounts, which are to be determined at trial, to the United States.

112. By this claim, the United States requests a full accounting of all revenues (and interest thereon) and costs incurred by Regeneron on sales of Eylea for Medicare patients whose co-pays CDF covered, and disgorgement of all profits earned and/or imposition of a constructive

trust in favor of the United States on those profits.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, the United States, requests that judgment be entered in its favor as follows:

I. On Counts I and II under the False Claims Act against Regeneron, for the amount of the United States' damages to be established at trial, trebled as required by law, and such civil penalties as are authorized by law, and all such further relief the Court deems just and proper.

II. On Count Three for unjust enrichment, for the damages sustained and/or amounts by which Regeneron retained illegally obtained monies, plus interest, costs, and expenses, and such further relief as may be just and proper.

III. All other and further relief as the Court may deems just and proper.

The United States hereby demands a jury trial on all claims alleged herein.

Respectfully submitted,

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